

## REMARKS

### The Specification

Applicants request entry of the benefit claim in this paper. The benefit claim was originally made in a Preliminary Amendment filed with the subject application. See Exhibits I and II for copies of the Preliminary Amendment and receipt, respectively. The Preliminary Amendment appears to have been lost by the Patent and Trademark Office and does not appear in the Image File Wrapper. Because the benefit claim was made upon filing, *i.e.*, it was timely, no fee is due for its entry.

### The Claims

Claims 3-15 are allowed.

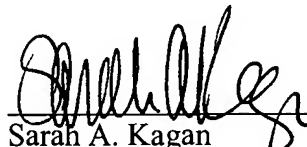
Claims 1 and 16-28 are cancelled by this amendment without prejudice to their future prosecution in a continuation or divisional application.

It is respectfully submitted that the application is now in condition for allowance.

Respectfully submitted,

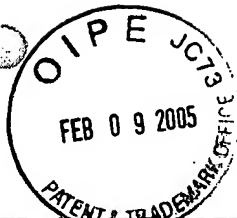
Dated: February 9, 2005

By:

  
\_\_\_\_\_  
Sarah A. Kagan  
Registration No. 32,141

Banner & Witcoff, Ltd.  
Customer No. 22907

# **EXHIBIT I**



**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

**Alessio FASANO**

Conf. No.: 0000

Continuation  
Appln. No.: of 10/095,450

Group Art Unit: 1653

Filed: August 27, 2003

Examiner: Snedden, S.

For: **PEPTIDE ANTAGONISTS OF ZONULIN AND  
METHODS FOR USE OF THE SAME**

**PRELIMINARY AMENDMENT**

Commissioner of Patents  
P.O. Box. 1450  
Arlington, VA 2231-1450

**FILED**

AUG 27 2003

Sir:

Prior to examining the above-identified application,  
please amend the application as follows.

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**PRELIMINARY AMENDMENT**  
**CONT of USSN 10/095,450**

**IN THE SPECIFICATION:**

Please enter the following amendments:

Page 1, between lines 6 and 7, the following is being inserted

This application is a Continuation of U.S. Patent Application No. 10/095,450, filed March 13, 2002 (now allowed); which in turn is a Divisional of U.S. Application No. 09/127,815, filed August 3, 1998 (now U.S. Patent 6,458,925); the disclosure of each of which is incorporated herein by reference.

Pages 40-54, delete in their entirety.

Pages 55-57, please renumber respectively.

**PRELIMINARY AMENDMENT**  
**CONT of USSN 10/095,450**

**IN THE CLAIMS:**

The status of the claims is as follows:

Claims 1-3. (Cancelled).

Claim 4. (New) A method for measuring zonulin levels in a body tissue or body fluid sample, said method comprising:

- (a) contacting said sample with an anti-zonulin antibody or an anti-ZOT antibody so as to form a complex between zonulin present in said sample and said antibody; and
- (b) detecting said complex.

Claim 5. (New) The method of Claim 4, wherein said method is an ELISA.

Claim 6. (New) The method of Claim 4, wherein said antibody is a monoclonal antibody.

Claim 7. (New) The method of Claim 4, wherein said antibody is a polyclonal antibody.

**PRELIMINARY AMENDMENT**  
**CONT of USSN 10/095,450**

**REMARKS**

The specification has been amended to insert formal matter and remove the present sequence listing.

The Examiner is requested to note that Applicants simultaneously file herewith a copy of the substitute Sequence Listing (which is considered to be a separate document by the U.S. Patent and Trademark Office) in PatentIn Version 2.1. Hence, the present Sequence Listing in the above-identified application is not necessary.

Claims 1-3 have been cancelled and new Claims 4-7 have been added.

Support for new Claims 4-7 can be found in the present specification, *inter alia*, at:

(A) Example 2, wherein production of anti-ZOT antibodies is disclosed;

(B) Example 3, wherein the use of anti-ZOT antibodies to assay for zonulin in various rabbit and human tissues is disclosed; and

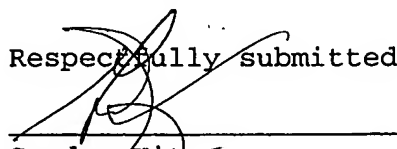
(C) Page 16, lines 15-25, wherein use of anti-zonulin antibodies to assay for zonulin in body fluids or tissues using, e.g., the method of Abrams, *Methods Enzymol.*, 121:107-119 (1986), i.e., an ELISA, is disclosed. A copy of Abrams is attached hereto.

Hence, the amendments to the specification, removal of the present Sequence Listing and the addition of new Claims 4-7 do not constitute new matter, and thus entry is requested.

**PRELIMINARY AMENDMENT**  
**CONT of USSN 10/095,450**

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

  
Gordon Kit

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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: August 27, 2003

## **EXHIBIT II**



REQUEST OF EARLY NOTIFICATION OF SERIAL NUMBER

Inventor: Alessio FASANO

Title: PEPTIDE ANTAGONISTS OF ZONULIN...

Atty Doc. #: A-8630 Client: UNIV OF MD,  
BALTIMORE

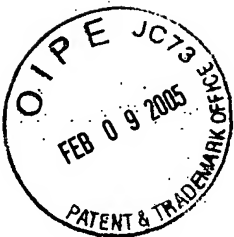
Filing Date: 08/27/03 # Pgs: 56/1 #Claims: 4

# Dwgs: 10 Decl yes Prelim Amdt yes  
Statement in Support (w/Seq. List): yes

IDS: yes Pr Doc: no Asgmt: in G-par Fee:  
\$750.00

☒ Check Attached/Check No. 229347 Atty: GK/vf

SERIAL NO.: \_\_\_\_\_



Cont of USSN 10/095,450



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